

CDPH UPDATE 2015

Routine Vaccine Management:
Temperature Monitoring, Handling
and Documentation
Best Practices

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Disclosure

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CINES FOR CHILDRE A LIFE OR NII A VFC

Objectives

By the end of this presentation, you should be able to:

- Identify proper storage units
- 2. Define acceptable temperature ranges
- 3. Explain how to record temperatures
- 4. Discuss types of thermometers
- 5. Explain what "calibration" means











Safeguarding Vaccines, Vaccine Emergencies and Reporting Out-of Range Temperatures



What is a "Vaccine Emergency"



Any of these situations can affect the temperature of the vaccine:

- Power Outage
- Appliance malfunction
- Weather conditions
- Accidental unplugging of the unit





Required Vaccine Storage Temperatures

OREFRIGERATOR

35°- 46° F (2°-8° C)

OFREEZER

Varicella, MMR, MMRV, Zostavax

+ 5° F (-15° C) or colder





CONFESTOR CHILDRE

Effect of temperature on vaccines

INACTIVATED VACCINES AND TOXOIDS

- Too cold (below 35°)
 - Immediate structural damage, regardless of the exposure time
- Too warm (above 46°F)
 - Damage is gradual, but cumulative exposure affects vaccine stability









Same price as the 2013 Lexus CT200

803 vaccine doses
15cu ft. refrigerator
\$32,000 worth of vaccine





Effective July 1, 2009, all enrolled VFC providers will be expected to comply with the new requirements. All newly enrolled providers or providers who experience any vaccine loss due to failure of their current storage unit (regardless of volume) will be expected to comply with the new requirement effective September 1, 2008.

Office Size	Required Equipment	
Very High Volume 10,000 doses/year	Pharmacy-grade refrigerator-only units and stand- alone freezer units	
High Volume 2,000-10,000 doses/year	Refrigerator-only (16.7 cubic feet minimum) and stand-alone freezer units	
Medium Volume 500-2,000 doses/year	Refrigerator-only (16.7 cubic feet minimum) and stand-alone freezer units	
Low Volume Less than 500 doses/year	OR Pharmacy-grade under the counter units.	

Best practices for vaccine storage

- Use the correct storage units
- ✓ Keep refrigerator temperatures between 35°F to 46°F. Aim for 40°F.
- ✓ Keep freezer temperatures at 5°F or below.
- Place thermometer probe towards the center of the vaccine storage unit
- Separate the VFC vaccine supply from privately purchased vaccine.
- Group vaccines by pediatric, adolescent, and adult types.
- Keep vaccines in their original boxes until you are ready to use them. Some vaccines are sensitive to light (HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines)
- Keep vaccines with shorter expiration dates to front of shelf.
- ✓ Transfer short-dated vaccine
 - ✓ If you have vaccine that will expire in 3-6 months, contact other VFC Providers to see if they can use the vaccine prior to the expiration date. Or call your VFC Rep.



Vaccine Refrigerator Setup

dates to front of shelf.

Expires in 9 months

Expires in

3 months

If you have vaccine that will expire in

3 months or less

that you will not be

able to use, notify

the VFC Program.

Storing Vaccines

Carefully organizing vaccines in a refrigerator helps protect vaccine and facilitates vaccine inventory management. Refrigerate all vaccines <u>except MMR</u>, MMRV, Varicella, and Zoster.

Refrigerator-only Unit

Always keep vaccine in its original box. Do not open the box until you are ready to use the vaccine.

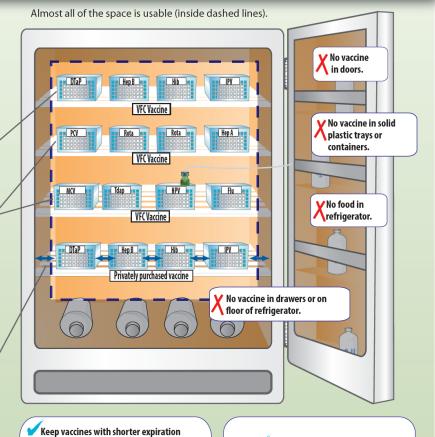
Place vaccine boxes in breathable plastic mesh baskets or directly on shelves. Label baskets or shelves by type of vaccine.

Group vaccines by pediatric, adolescent, and adult types.

Separate VFC vaccine from privately purchased vaccine and label them clearly.

Keep baskets 2-3 inches from walls and other baskets.

Store only vaccine and other medication in vaccine storage units.



Keep temperatures between

Below 35°F

is too cold!

Call VFC.

35°F to 46°F.

Above 46°F

Call VFC.

is too warm!









What NOT to do...

- No vaccine in doors, along walls
- No vaccine in drawers or on floor of refrigerator
- No vaccine in solid plastic trays or containers
- No food or lab specimens in refrigerator
- Never plug into outlet controlled by wall switch

DO NOT IGNORE OUT OF RANGE TEMPERATURES





9

What's wrong with this picture?









Everything!

- Dormitory-style unit
- Ice in freezer unit
- Too much vaccine for size
- Soda in the door
- Lab specimen in the fridge
- Vaccine on top shelf probably frozen







Temperature Monitoring, Equipment, and Equipment Maintenance (Calibration)



Thermometers

- Thermometers are an essential component of vaccine management. They help make sure vaccines administered to patients have been appropriately stored within manufacturer's recommended ranges.
- Every unit storing vaccines must have a thermometer that meets the following specifications: but one that is accurate, provides minimum and maximum temperatures reached over a period of time, and it is well-maintained (calibrated annually).







Thermometers & VFC

- VFC providers must have VFCcompliant thermometers in the practice's vaccine storage units at all times.
 - A primary thermometer must be centrally located in each vaccine storage unit in proximity with vaccines.
 - A minimum of one back-up thermometer, located in an easily accessible practice area, must be available for use when primary thermometers are being calibrated or fails.

Practices with multiple vaccine storage units may need more than one back-up thermometer.







Thermometer Specifications

Display current, minimum and maximum temperatures.

Have an alarm

Be within +/-0.5°C (+/-1°F) accuracy.



External digital display to monitor temperatures without opening unit

Have a min / max reset button

biosafe glycolencased probe (or similar buffered solution).





Unacceptable Thermometers











Fluidfilled biosafe liquid bi-metal stem

food

household mercury

Chart recorders

-difficult to read

-failure to change the chart paper will result in unusable temperature data.

- have significant limitations in temperature monitoring
- can be difficult to read and only indicate the temperature at the precise time they are read
- temperature fluctuations outside the recommended range are not detected.



Probes are available in two forms: a standard probe that will measure air temperature and a biosafe glycol-encased probe that will measure liquid temperature.

Standard probes that measure air can be easily affected by short fluctuations in air temperature in the unit such as cycling and frequent opening and closing of the unit doors during busy workdays.

Glycol-encased probes can provide a more accurate reading of actual vaccine temperature and are therefore recommended by CDC





Thermometer Probe Placement

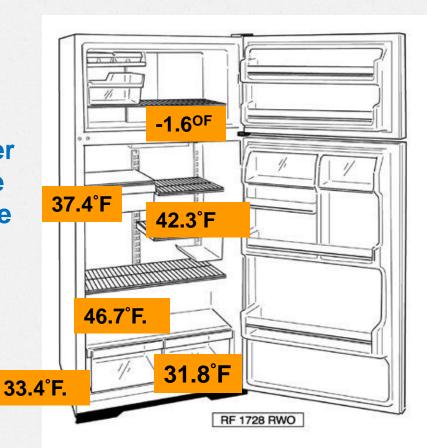
- Thermometer probe placement within the unit is just as important as thermometer selection.
- The thermometer should be in proximity to the vaccines being stored.
- Thermometers should not be placed in the doors, near or against the walls, close to vents, or on the floor of the unit.
 - According to a 2009 NIST study, thermometers "attached to walls or hanging in the air recorded dramatic temperature spikes followed by a significant drop well below the 2°C limit."

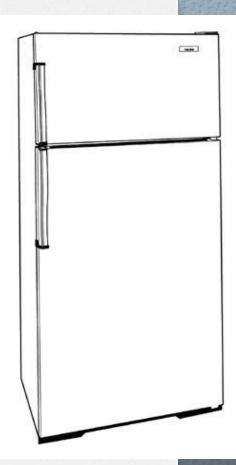




Temperatures vary within one unit

Place thermometer probe in the center of the unit.





VACCINES for CHILDREN





How to Buy a Vaccine Thermometer

- Begin your online search
 - Narrow search by including key terms such as "High accuracy vaccine thermometers", "±0.5C accuracy vaccine thermometer"



Cole-Parmer Remote-Monitoring Thermocouple Thermometer (Deg. C)

\$28.00 from Cole-Parmer

Ultra-thin cable lets you measure within doored equipment. For use in remote measurement applications.



Control Company Traceable® High Accuracy Refrigerator Digital ...

\$109.92 from Nova-Tech International 1 seller review

"Control Company Min/Max Traceable High Accuracy Refrigerator Digital Alarm Thermometer with Two



Vaccine Thermometer, 5mL

\$77.90 from Devine Medical

Accurately monitor temperatures in zers, water baths, heating blocks, incubators, and refrigerators with th



Control Company Traceable® High Accuracy Refrigerator Digital ...

\$97.78 from Nova-Tech International 1 seller review

"Control Company Min/Max Traceable High Accuracy Refrigerator Digital Alarm Thermometer with one v



Alarm Thermometer - 1 Probe

\$79.10 from Devine Medical

Alarm Thermometer - 1 Probe High accuracy indicators are perfect for monitoring temperatures in refrige



Tip Temp COCSEN012 Wireless Remote Thermometer

\$110.95 from HomeTech Solutions *** 412 seller reviews

Read temperatures 100 feet away: Module transmits on a radio frequency of 433 MHz, penetrating walls, v





ALC.

Do an online search

- Do not base your order on just an image!
- Read product specification carefully
 - Look for thermometers with a digital display of current, minimum, and maximum temperatures
 - Check that the digital display can be attached to outside of the vaccine storage unit
 - Check specifications for accuracy of ±1°F (±0.5°C) or better (±0.3°C, 0.1°C)
 - Check specifications for a temperature probe in a glycol-encased (or similar buffer solution*) in a bottle
 - Check specifications for a visual or audible alarm for out-of-range temperatures
 - Check that the thermometer will have a certificate of calibration http://eziz.org/assets/docs/IMM-1119.pdf)





VACCINES for CHILDREN C.A.L.I.F.O.R.N.I.A.

Are These Thermometers OK?













It depends.....Check specifications!

Description

Specifications

More Info

Accessories

Protect your valuable refrigerated and frozen products with the PharmAlarm 1 Digital Alarm Thermometer. It monitors critical temperatures with audible and visual alarms. Alarm LED stays illuminated even if system returns to normal conditions.

Select ambient monitoring with an internal temperature sensor, or display temperatures via an external glass-bead filled temperature vial. The PharmAlarm 1 measures accurately from -50 to 70°C (-58 to 158°F). Each unit features a large digit display for ease in reading current temperature and a push-button backlight. Rest the PharmAlarm 1 on a shelf with a convenient kickstand or attach to the side of fridge/freezer with magnetic rear mounts.

Each PharmAlarm 1 ships with one external temperature sensor housed in a vial of glass beads that more accurately measures biopharm stored chilled products. Also included is a 3-point NIST-Traceable calibration certificate with test data at -20, 25, and 50°C.

Description Sp	ecifications	More Info	Accessories		
Internal Range	14	to 122°F (-10 to 5	:0°C/		
External Range		to 158°F (-50 to			
Accuracy		±1°F (±0.5°C) between -4 to 122°F (-20 to 50°C), otherwise ±1.8°F (±1°C)			
Resolution	0.1				
Display		0.8 H x 1.9 W inches (21 H x 48 W mm)			
Alarms	Hig	High and low alarms settable in 1.8°F / 1.0°C increments			
Battery	3 v	3 volt, CR2032 or equivalent x 1 piece (included), 10,000 hours			
Response	10	10 seconds			
Probe Cord Length		39.4 L inches (1 L m)			
Dimensions	2 H	1 x 2.9 W x 0.7 D	inches (52 H x 73 W x 18 D a	mm)	
Calibration	MIS	T-Tracophia cort	ificate included, 3-point (-20,	25 and 50°C)	

Specifications				
Product Type	Digital Indicator			
Min temperature (° C)	-50			
Min temperature (° F)	-58			
Max temperature (° F)	158			
Dimensions (" W)	3.875			
Dimensions (" H)	4.375			
Max temperature (° C)	70			
Alarm	Yes			
Dimensions (" D)	0.875			
Accuracy (° F)	±1°			
Accuracy (° C)	±1°			
Display	LCD, triple display, 1.			
Probe dimensions	10-ft cable submerse			





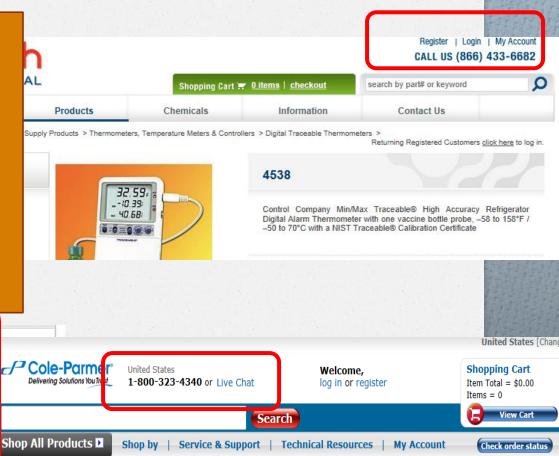
VFC

When in doubt... ask!

View Product List

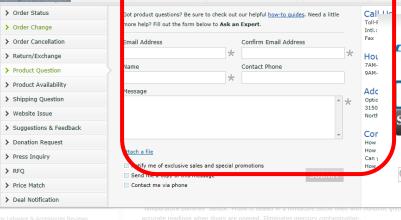
< 2 of 2

• Contact the vendor directly for an explanation of the thermometer features and functions, or if you are unclear about specifications or acronyms listed in sales materials, such as buffering media, GRAS (Generally Regarded As Safe) solution.



Home > Temperature, Humidity, Moisture and Weather Products > Temperature Products > Thermocouple Meters / Probes

Handheld Thermocouple Meters > Cole-Parmer Remote-Monitoring Thermocouple Thermometer



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Become Familiar with the Thermometer

r

Remember these important steps:

- Practice and test your new thermometer to become familiar with it BEFORE you place it in the vaccine storage unit to measure temperatures
 - Test alarm settings to make sure they work
 - 2. Practice resetting temperature readings
 - 3. Train and verify competency of thermometer use among all staff responsible for temperature monitoring

66DON'T PRACTICE UNTIL YOU GET IT RIGHT.

> PRACTICE UNTIL YOU CAN'T GET IT WRONG.99





CONESTOT CHILDR CALLEORNII VFC

Thermometer Calibration

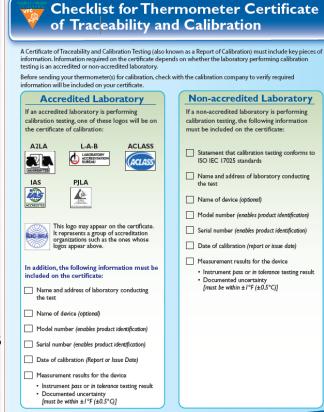
- The word "calibrate" is often misunderstood to mean making some kind of adjustment to a thermometer for accuracy.
- While adjustments are sometimes needed, "calibrating" a thermometer simply means testing its accuracy against a verifiable standard.
 - If the thermometer is within the accuracy specification listed by the manufacturer or quality control agency, it should not be adjusted
 - Accuracy of a thermometer is its ability to measure temperature correctly without error.
- A thermometer must be within ±1°F (±0.5°C) of the actual temperature to be considered an accurate device.



Thermometer Calibration & Certification

- All thermometers (primary and back-up) must be calibrated annually (or every other year when the manufacturer recommends calibration done in a period that is longer than two years), and have a valid Certificate of Traceability and Calibration Testing, also known as a Certification of Calibration.
- A valid Certification of Calibration must be kept on file according to recordkeeping requirements and be readily available for review during VFC visits.
- Calibration should be conducted by an accredited laboratory.
- Thermometer no longer accurate within +/-1°F (+/-0.5°C) as indicated in calibration measurement results must be replaced.

When sending your thermometers for calibration make sure to share items in the Calibration checklist with the calibration lab!



eziz.ora

Accredited Laboratory



Calibration complies with ISO/IEC 17025, ANSI/NCSL Z540-1, and 9001



Cert. No.: 4227-5559302

Traceable® Certificate of Calibration for Re

thermometer identification

Instrument Identification:

Model: 4227

S/N: 130736898

Manufacturer: Control Company

Calibration date and next date due

Accuracy

Standards/Equipment:

Description	Serial Number	<u>Due Date</u>	NICT CADIE KEIL
Temperature Calibration Bath TC-179 Thermistor Module Temperature Probe	A45240 A17118 128	2/13/14 2/20/14	1000332071 6-B48Z9-30-1
Temperature Calibration Bath TC-231 Thermistor Module Temperature Probe	A79341 A17118 3039	2/13/14 2/20/14	1000332071 6-B48Z9-1-1

Certificate Information:

Technician: 68

e: CAL-03 Proce/

Cal Date: 12/04/13

Cal Due: 12/04/15

Test Conditions:

24.0°C

0 %RH 1009 mBar

Calibration Data: (New **Calibration Data** Min Max As Left In Tol lominal Nominal Unit(s) 0.100 >4:1 Y -0.5 0.5 0.0 N.A. 0.000 °C Probe 0.058 >4:1 49.5 50.5 49.9 N.A. 50.000 *C Probe

This Instrument was calibrated using Instruments Traceable to National Institute of Standards and Technolog

Accredited Laboratory Name

A Test Uncertainty Ratio of at least 4:1 is maintained unless otherwise stated and is calculated using the expanded measurement uncertainty. Uncertainty extends an accordance with the ISO "Guide to the Expression of Uncertainty in Measurement" (GUM). The uncertainty represents an expanded test and is calculated in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement" (GUM). The uncertainty represents an expanded test and is calculated in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement" (GUM). The uncertainty of the measurement is a calculated in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement" (GUM). The uncertainty represents an expanded test and is calculated in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement" (GUM).

e results contained

CONTROL COMPANY 4455 Rex Road Friendswood, TX 77546

Phone 281 482-1714 Fax 281 482-9448 service@control3.com www.control3.com

ty Ratio;

Sectrol Company is an ISO 17025 Calibration Laboratory Accredited by (A2LA) American Association for Laboratory Accreditation, Certificate No. 1750.01 Control Company is ISO 9001 Quality Certified by (DNV) Det Norske Verites, Certificate No. CERT-01805-AQ-HOUinternational Laboratory Accreditation Cooperation (ILAC) - Multilateral Recognition Arrangement (MRA)





Unacceptable Proof of Calibration



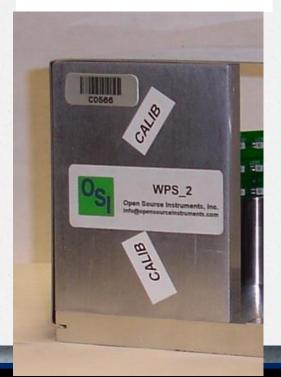
CALIBRATION BY___ DATE ____ NEXT CAL. DUE ____ INSTRUMENT#



TTE (800) 242-6022 Company S/N: X99998X ID: Jane Jones Date: 1/16/2003 By: AZ

Next Due: 7/16/2003









Calibration Services

- Thermometer calibration must be done by a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body.
- Follow links for listings of accredited laboratories:
 - The American Association for Laboratory Accreditation (A2LA)
 - http://www.a2la.org/dirsearchnew/newsearch.cfm
 - Laboratory Accreditation Bureau (L-A-B)
 - http://www.l-a-b.com/content/directory-accredited-labs
 - ANSI-ASQ National Accreditation Board (ACLASS)
 - http://www.aclasscorp.com/search-accredited-companies.aspx
 - International Accreditation Service (IAS)
 - http://www.iasonline.org/Calibration_Laboratories/CL.html
 - Perry Johnson Laboratory Accreditation, Inc.(PJLA)
 - http://www.pjlabs.com/search-accredited-labs





Temperature Monitoring



- Temperatures for each unit (current, MIN & MAX) must be read and documented twice daily
 - logs must be maintained for 3 yrs. and be readily available for review (during site visits or as requested by VFC during random temp log reviews).
 - Min / max temperatures must be cleared after <u>each</u> reading.
 - Temperatures must be recorded on VFC-provided temperature logs, even if using a continuous temperature-recording device or digital data logger.



PRefrigerator Temperature Log

Four Steps to Protect Your Vaccines.

Avoid patient recalls by accurately recording temperatures twice a day.

Step 1	Step 2	
cord the Time and ur Initials.	 Record CURRENT, MIN, and MAX temperatures. Circle if TOO WARM or TOO COLD. Refer to ranges. 	
1 1		

	-	—	—	-	—	→	—
Day of Month	Time 8:00 a.m.	Initials NN	CURRENT 364	MIN (31.0)	MAX 40.2	ТОО	MAX TOO WARM?
xample 1	4:00 p.m. a.m.	TP	46.7	39.2	48.3	WARM! 54° & warmer 53°	Press MEMORY CLEAR/RESET Post "Do Not Use Vaccine" sign Alert your supervisor.
2	p.m. a.m.					52° 51°	4. A.M. – Call VFC Call Cente
3	p.m. a.m. p.m. a.m.					50° 49° 48° 47°	P.M. – Wait 1 hour: • If CURRENT is still TOO W call VFC Call Center. • If CURRENT is OK, no need to call VFC Call C
4	p.m.					46.1°	5. Document on Step 4 (next pa
6	р.т. а.т. р.т.					OK 46.0° 45°	
7	a.m.					44° 43° 42° 41°	CURRENT, MIN, and M/ are all OK.
9	a.m. p.m. a.m.					40° 39° 38°	Done. Skip Step 4 (next page
10	p.m. a.m. p.m.					37° 36° 35.0°	
11	a.m. p.m.					тоо	MIN TOO COLD?
12	а.т. р.т.					34.9°	Press MEMORY CLEAR/RESET I Post"Do Not Use Vaccine" sign
13	a.m. p.m.					34° 33° 32°	Alert your supervisor. At any time – Call VFC Call
14	а.т. р.т.					31° 30°	5. Document on Step 4 (next page
15	a.m. p.m.	 				29° 28° & colder	

When Log Is Complete Sign and Acknowledge. File and keep log for 3 years.

I certify that the temperatures recorded on this log are correct. All temperatures that were TOO WARM or TOO COLD have been circled and corrective action was take
and documented. I understand that falsifying logs will result in vaccines being unusable, patients being revaccinated, and provider possibly replacing vaccines.

Staff Names and Initials:	
On-site Supervisor's Name & Signature:	Da

California Vaccines for Children Program (VFC) 1-877-243-8832

EZIZ.org IMM-1125 Page 1 (12/14)

Follow steps for one of the

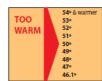
three ranges.

Refrigerator Temperature Log

Month/Year (Days 1-15)	
Refrigerator Location	
Refrigerator ID	
VEC PIN	

Step 4

Document actions for temperatures that are TOO WARM or TOO COLD.





Fill out this section if you recorded a MAX that was TOO WARM.

	•						OU WAR	-	
Date & Time	Incident	Incident Called VFC? Corrective Action Results			Temperatures 1 hour after reset			How long temps TOO	Initia
Time					CURRENT	MIN	MAX	WARM?	
Example	MIN temp. 31.0, too cold. Over-adjusted thermostat.	Yes	Called VFC and manufac- turers, adjusted thermostat to warmer setting.	Vaccine not usable, returned to McKesson, recalled patients. Refrigerator serviced. Temps stabilized.	1	1	1	1	NN
ixample	Temps went up during inventory when doors were opened a lot.	No	Reset thermometer, added water bottles, kept door shut, and cheeked temps in 1 hour.	Temperatures returned to OK range.	42.5	42.5	46.7	30 min.	TP

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www.EZIZ.org IMM-1125 Page 2 (12/14)



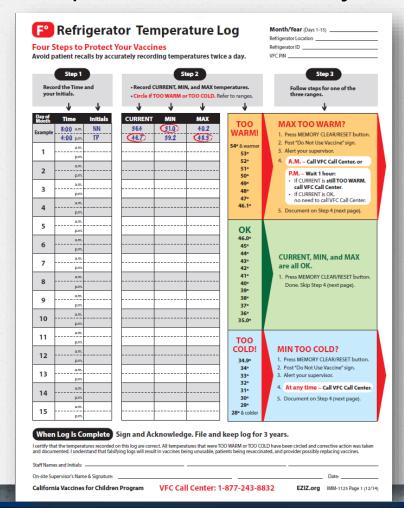




2015 Temperature Logs



Implement immediately



			our Vaccir rately record		eratures twic	e a day.	VFC PIN
	Step 1 rd the Time an Initials.	d		URRENT, MIN	ep 2 I, and MAX ten		Step 3 Follow steps for one of the two ranges.
	4	↓	•	1	1	1	V
Day of Month		Initials	CURRENT	MIN	MAX	тоо	
xample	8:00 a.m. 4:00 p.m.	TP	-1 5.0	-1 0.5 -20.4	-10.8	WARM! 18° & warmer	MAX TOO WARM? 1. Press MEMORY CLEAR/RESET button.
1	a.m.					17° 16°	Press MEMONT CLEAN/RESET BUTTON. Post "Do Not Use Vaccine" sign. Alert your supervisor.
2	a.m.					15° 14°	4. A.M. – Call VFC Call Center, or
3	p.m.					13° 12°	P.M. – Wait 1 hour: If CURRENT is still TOO WARM.
4	a.m.					11° 10° 9°	call VFC Call Center. If CURRENT is OK, no need to call VFC Call Center.
5	a.m.					8° 7°	Document on Step 4 (next page).
6	a.m.					6° 5.1°	
7	a.m. p.m.					ок	
8	a.m. p.m.					5.0° 4°	
9	a.m. p.m.					3° 2° 1°	
10	a.m. p.m.					0° -1°	CURRENT, MIN, and MAX
11	a.m. p.m.					-2° -3°	are all OK. 1. Press MEMORY CLEAR/RESET button.
12	a.m. p.m.					-4° -5° -6°	Done. Skip Step 4 (next page).
13	a.m.					-7° -8°	
14	a.m.					-9° -10s°	
15	a.m.					-20s° -30s° & colder	
certify tha ocumente	t the temperatur	es recorded o	n this log are corre	ct. All tempera	tures that were TO	keep log for and the been seen to be been seen to be been seen to be a	3 years. circled and corrective action was taken and and provider possibly replacing vaccines.



Refrigerator Action Guide – When To Call VFC (°F)

Action steps are different because vaccines respond differently to WARM and COLD temperatures and the amount of time at these temperatures. Post this guide on the refrigerator to help you take the correct actions.

VACCINES FOR CHILDREN C. A. L. D. F. O. R. N. I. A.

MIN TOO COLD

28° & colder 29° 30° 31° 32° 33° 34° 34.9°

- Press MEMORY CLEAR/RESET button(s) after recording temperatures.
- Post "Do Not Use Vaccine" sign.
- Alert your supervisor.

Call VFC Call Center! 1-877-243-8832

Press MEMORY CLEAR/RESET button(s).

Document all actions taken.

CURRENT, MIN, and MAX are all OK.

35.0° 36° 37° 38° 39° 40° 41° 42 43° 44° 45° 46.0°

 Press MEMORY CLEAR/RESET button(s). Done. No need to call VFC.

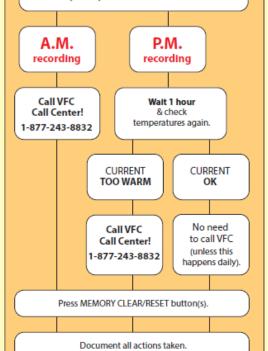


Make sure that MIN and MAX show on the display and not alarm settings (LO and HI).

MAX TOO WARM

46.1° 47° 48° 49° 50° 51° 52° 53° 54° & warmer

- Press MEMORY CLEAR/RESET button(s) after recording temperatures.
- 2. Post "Do Not Use Vaccine" sign.
- 3. Alert your supervisor.



If you are not sure if there is a problem, call:

California Vaccines for Children Program (VFC) 1-877-243-8832





- If a cold chain failure is suspected (temperatures outside the recommended temperature range), providers must:
 - Store vaccine under correct temperature storage conditions.
 - Label the vaccine "DO NOT USE" so the vaccine is not administered until a response indicating the vaccine is acceptable for use has been received.
 - Notify the VFC program immediately after discovery of the incident.
 - Follow the guidance on documenting and reporting the incident to the vaccine manufacturers for a resolution.





- VFC Requirements:
 - Maintain updated plans
 - Reviewed annually & document review
 - Update as needed

Routine and
Emergency
Management
Plans

New!

VFC Providers must develop and maintain a Routine Vaccine Management Plan and an Emergency Vaccine Management Plan. Plans should include practice-specific guidelines, protocols, and contact information. Plans must be updated whenever VFC Program guidelines change and when staff with designated vaccine management responsibilities change.







Vaccine Management Plans



Routine Vaccine Management Plan

INVENTORY MANAGEMENT

- A physical vaccine inventory is conducted at least once a month and before ordering vaccine.
- The practice has enough vaccine supply to meet the needs of its VFC-eligible patients.
- The practice may keep up to two-weeks additional supply to mitigate shortages in the event of shipment delays.
- The practice uses an inventory control system, i.e., usage log, which documents each patient, vaccine type, lot number, and date of administration.
- The practice maintains accurate records, including purchase invoices, for privately purchased vaccines and makes them available upon request to VFC Representatives.
- Vaccine that is drawn up and not used is disposed of properly.
- When diluent is packaged with vaccine, the practice stores them together. When diluent is not packaged with its vaccine, the diluent is clearly labeled and stored where it can be easily identified.

STOCK ROTATION, RETURNS, AND TRANSFERS

- The practice organizes vaccines so those with the shortest expiration dates are used first.
- The practice returns expired and/or spoiled vaccine to McKesson for excise tax credit within three months of expiration/spoilage.
- If the practice has vaccine due to expire within three months and it will not be used, it:
 - Notifies the VFC Program about the vaccine;
- Requests a transfer approval from the VFC Program through MyVFCVaccines; and
- Identifies VFC providers in the area to contact and inquires if they may be able to use the soon-toexpire vaccines.
- If a practice transfers or transports vaccine, it follows VFC Program guidelines, and completes the appropriate

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- If vaccine becomes spoiled or expires, staff remove it immediately from the storage unit, report it to the VFC Program, and complete the appropriate documentation
- The practice may return unused vials/prefilled syringes to McKesson if unopened and in original packaging.
- The following vaccine supplies should not be returned:
 - Used syringes with or without needles
 - Syringes with vaccine drawn up and not used
- Broken or damaged vaccine vials
- Multi-dose vials that have already been withdrawn
- Vaccine that is spoiled or expired must be reported to the VFC Program before a new order can be submitted.

Vaccino Ordorina

- According to the VFC Program, we are (check one):
- Large-sized provider and receive more than 2,000 vaccine doses/year. Our VFC-assigned order frequency is monthly.
- ____ Medium-sized provider and receive 500-2,000 vaccine doses/year. Our VFC-assigned order frequency is every two months.
- ___ Small-sized provider and receive fewer than 500 vaccine doses/year. Our VFC-assigned order frequency is quarterly.
- Orders are submitted on MyVFCVaccines and are placed according to clinic-based eligibility data, assigned order frequency, vaccine usage, and take into account the inventory in stock.
- When a vaccine is offered by two or more manufacturers, the practice orders one brand to mitigate administration errors.
- The practice does a physical inventory before placing a vaccine order.
- The practice orders all the vaccines it needs before the next assigned order.
- A summary of on-hand inventory is included with each order.

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Routine Vaccine Management Plan

VACCINE STORAGE UNITS/LOCATIONS AND MAINTENANCE

Maintenance/Repair Company: Phone:

UnitType	Location (Room#)	Brand	Model	Type of Service	Date
Refrigerator					
Freezer					
ocation of co	mpleted Tempe	arature Logs:			

THERMOMETER MAINTENANCE

Calibration Company/Laboratorys Contact Phone:

Calibration Company/Laboratorys Contact Phone:

Location of Cartificates of Calibration:

Location of Back-up Thermometers:

Thermometer model/serial number:	Primary?	BackUp?	Calibration Date:	BatteryReplace- reent Date:	Alaran Setting Low	Aların Setting High

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Routine Vaccine Management Plan

SIGNATURE LOG

By signing, I acknowledge I have reviewed and am familiar with the information in this document.

Review Date:	
Updates & Comments:	
Provider of Record name:	Signature:
Vaccine Coordinator name:	Signature:
Back-up Vaccine Coordinator name:	Signature:
Additional Staff:	Signature:

Review Date:	
Updates & Comments:	
Provider of Record name:	Signature:
Vaccine Coordinator name:	Signature:
Badt-up Vaccine Coordinator name:	Signature:
	1-3
Additional Staff:	Signature:

Review Date:	
Updates & Comments:	
Provider of Record name:	Signature:
Vaccine Coordinator name:	Signature:
Badk-up Vaccine Coordinator name:	Signature:
Additional Staff:	Signature:

Review Date:		
Updates & Comments:		
Provider of Record name:	Signature:	_
Vaccine Coordinator name:	Signature:	
Back-up Vaccine Coordinator name:	Signature:	_
<u>'</u>		
Additional Staff:	Signature:	





Emergency Vaccine Management Plan

WORKSHEET FOR EMERGENCY CONTACTS KEEP NEAR VACCINE STORAGE UNIT(S)

The California VFC Program requires each practice to develop and maintain an Emergency Vaccine Management Plan and a Routine Vaccine Management Plan Plans should include practice-specific guidelines, protocols, and relevant contact information. Plans must be updated and reviewed whenever VFC Program guidelines change and when staff with designated vaccine management responsibilities change.

This Emergency Vaccine Management Plan outlines actions staff should take in the event of an emergency that might affect vaccine viability. Examples include unit malfunction/mechanical failure, power outage, natural disaster, or human error.

STAFF ROLES & CONTACT INFORMATION

DIFFICE/ CLINIC HAND	VFC FIN HUNBER:
ADDRESS:	

In an emergency, contact the following people in the order listed:

Role/Responsibility	Hame	Phone Humber	Alt Phose Humber	Ereal Address
1.				
2.				
3.				
4.				

USEFUL EMERGENCY NUMBERS

Service	Hame	Phone Humber	Alt Phose Humber	Email Address
VFC Field Rep				
VFC Customer Service Center		1-877-243-8832		
Utility Company				
Building Maintenance				
Building Alarm Company				
Refrigerator/Freezer Alarm Company				
Refrigerator/Freezer Repair				
Generator Repair and Maintenance				
Point of contact for Vaccine Transport				
Other				

Does the clinic have a generator? If so, where is it?

If your clinic does not have a generator, and/or your vaccine storage unit fails, it might be necessary to transport vaccine to alternate storage locations.

Alterante Vaccise Storage Locations	Address	Phone Humber	Alt Phone Number	Email Address

Location of emergency packing supplies:

www.eziz.org

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California Department of Public Health, Immunization Branch

IMM-1123 (11/13)

Emergency Vaccine Management Plan

RELOCATING VACCINE

If a power outage is long-term, is not expected to be restored by the end of the day, or vaccine storage units have reached out-of-range temperatures, prepare to relocate vaccines to the alternate storage location as feasible.

Before transporting vaccines

- Review job aids (http://www.aziz.org/assets/docs/ IMM-983.pdf and http://eziz.org/assets/docs/IMM-1130.pdf)
- Contact the alternate storage facility to verify they can accept the vaccines
- Notify the VFC Program.

If transport or relocation is not feasible, e.g. alternate location not available or unsafe travel conditions:

- Keep units closed and document the temperatures (CURRENT, MIN, MAX).
- Contact the VFC Program.

Packaging and Transporting Vaccines

- Complete the Refrigerated Vaccine Transport Log and/or the Frozan Vaccine Transport Log (http:// exiz.org/assets/docs/MM-1132.pdf and http://exiz. org/assets/docs/MM-1116.pdf).
- Prepare cooler(s) following VFC guidelines job aids. (http://www.eaiz.org/assets/docs/MMM-983.pdf and http://aziz.org/assets/docs/MMM-1130.pdf) Notify the key staff listed on this Emergency Plan as appropriate.
- Pack vaccine according to VFC guidelines.
 - Use frozen cold packs for frozen vaccines; never use dry ice.
- Use conditioned frozen packs for refrigerated vaccines. Placing refrigerated vaccine directly on frozen packs and packaging it without sufficient insulation may freeze and therefore damage vaccine. If clinic does not have time to condition frozen packs, refrigerated cold packs or cold water bottles may be used.
- Package and prepare diluent.
 - MMR, Varicella and MMR-V diluent can be stored at room temperature or in the refrigerator.

- Diluents stored in the refrigerator should be transported with refrigerated vaccines.
- Diluents stored at room temperature should be transported at room temperature.
- Diluents packaged with their vaccine should be transported with the vaccine
- Upon arrival at the alternate vaccine storage location, document total vaccine transport time, the temperatures (CURRENT, MIN, and MAX) in the transport cooler(s) and the alternate storage units).

AFTER POWER IS RESTORED

- Verify storage units are functioning properly before attempting to move any vaccine
- Follow the same transportation procedures and transfer vaccine back to its original storage unit.
- Vaccine kept at the proper temperature during the power outage, whether transported or not, may be used.
- For any vaccine not stored at the proper temperature:
 - Segregate it in the storage unit.
 - Markit*DO NOTUSE*
 - Contact the VFC Program; be prepared to provide timeframes and temperature information.
- Never return vaccine to the vaccine distributor without VFC Program authorization.

Page

CDPH



EZIZ Lessons Requirement

Lessons	Vaccine Coordinator	Back-up Vaccine Coordinator	Provider of Record	Provider of Record Designee
VFC Program Requirements *	✓	√	√	√
Storing Vaccines *	✓	\checkmark	\checkmark	✓
How to Record Refrigerator Temperatures	✓	\checkmark	\checkmark	\checkmark
How to Record Freezer Temperatures	✓	\checkmark	\checkmark	\checkmark
Conducting a Vaccine Inventory*	✓	\checkmark	Recommended	Recommended

^{*} Test Out Option Available





EZIZ TRAINING





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Storage & Handling

Resources

Don't forget

to download helpful job aids for all the lessons





Sign up to receive **EZIZ** news and **VFC letters** via emai!

Learning History

California VFC Recertification Requirement 2015

The Lessons below must be completed for 2015 recertification. Providers cannot recertify until the training has been completed.

- † required for Vaccine Coordinator 1 and Backup 1
- required for <u>Provider of Record</u> and <u>Designee</u>

RESET Restart lessons if taken before 2015. You may skip lessons if you meet these requirements.

When done, log in to MyVFCVaccines to get credit.

Lesson	Pre-lesson Check	Instruction	Post-lesson Check	Certificate
Storing Vaccines † ‡	✓	Review (Optional)	Test-Out 01/07/2015	Print
How to Record Refrigerator Temperatures (PDF) † ‡	N/A	Begin F° / C°	N/A	
How to Record Freezer Temperatures (PDF) † ‡	N/A	Begin F° / C°	N/A	
Conducting a Vaccine Inventory †	✓	Review (Optional)	Test-Out 01/07/2015	Print
VFC Program Requirements †	✓	Continue		
Preparing Vaccines	Begin			
Administering Vaccines	Begin			

My Account

Hi csadorra,

- Edit Profile
- Reset individual lessons
- Automatically reset all lessons for recertification [NEW]
- Logout

To skip the lesson (test-out), you must have completed the required lesson in 2014 with a passing score, and click the RESET button to restart the required lesson for 2015, and pass the pre-lesson

- More Demonstration Videos:
 - Pre-filled Syringes
 - Nasal Vaccines
 - Oral Vaccines
 - O Educating Parents
 - Documentation
 - o Safety

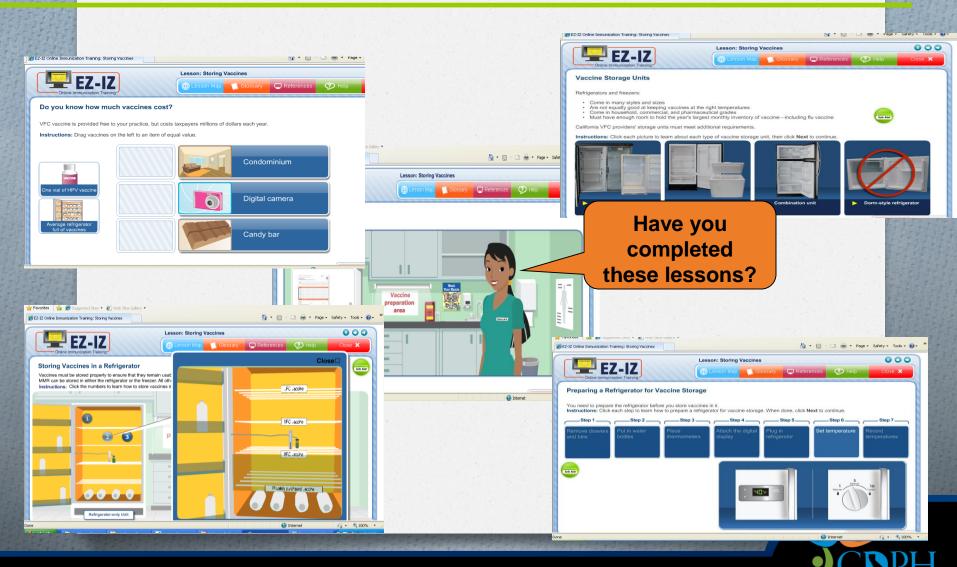
Technical Support

For answers to the most common problems or to contact EZIZ Training technical support, go to EZIZ Training Frequently Asked Questions.





EZIZ Lessons







VFC RECERTIFICATION





















The VFC-eligible patient population has been pre-filled for your practice based on usage data reported by your practice. Review and confirm or modify the patient population estimates for your practice.

Patient Estimates							
ESTIMATED NUMBER OF VFC AND NON-VFC ELIGIBLE PATIENTS 0-18 YEARS WHO WILL RECEIVE IMMUNIZATION IN YOUR PRACTICE DURING A 12-MONTH PERIOD (JANUARY-DECEMBER 2015). ENTER -0- IF THERE ARE NO PATIENTS IN THE CLINIC WITHIN ANY OF THE LISTED CATEGORIES.							
(Note: these numbers are calculated based on your VFC vaccine usage history. Revise the numbers if necessary.)							
Category	< 1 yr	Ages 1-6 yrs	Ages 7-18 yrs	TOTALS			
category	Number of patients *	Number of patients *	Number of patients *	TOTALS			
TOTAL VFC Eligible	0	0	0	0			
1. CHDP/Medi-Cal Eligible	0	0	0	0			
2. Uninsured	0	0	0	0			
3. Am. Indian/Alaska Native	0	0	0	0			
4. Underinsured (FQHCs and RHCs only)	4. Underinsured (FQHCs and RHCs only) Underinsured children may be immunized with VFC-supplied vaccines ONLY at FQHCs and RHCs. This option does not apply to your provider type.						
Non-VFC Eligible		0					
ALL CHILDREN	0						
% of patients 0-18 yrs of age in your practice who <u>are vfc-eliqible</u> : NaN							
What data source did you use to confirm/modify your patient population estimates?							
In the last year, has the number of children you immunize?							
Check this box ONLY if you don't have any non-VFC eligible patients $\ egin{array}{c}$							
I certify that my practice will order and provide all age-appropriate ACIP-recommended vaccines to my VFC-eligible patient populations. Below are the age-appropriate ACIP-recommended vaccines that I will provide based on my patient estimates. If I have patients ages 1 year or younger, I will order and provide the following vaccines: DTaP, Hep B, Hib, Influenza, Polio, Pneumococcal Conjugate, Rotavirus, If I have patients ages 1-6 years, I will order and provide the following vaccines: DTaP, Hep A, Hep B, Hib, Influenza, Polio, Pneumococcal Conjugate, MMR, Varicella, If I have patients ages 7-18 years, I will order and provide the following vaccines: HPV, Influenza, Meningococcal Conjugate, Tdap							
I certify that I have reviewed the provided patient estimates. I have edited or confirmed the estimates and they are a true reflection of my pediatric patient population according to the data source selected							
te required field i = more information							









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Contact VEC

Phone: 1-877-243-8832 Business hours: 8:30-5 Fax: 1-877-329-9832

- Find a VFC field representative in your
- Find other VFC provider offices in your area
- Send us your comments at eziz@cdph.ca.gov

Sign up to receive EZIZ news and **VFC letters** via emai!



California VFC Program



Overview Find out how to become a California VFC provider.



Storage and Handling Learn about VFC

equipment requirements and how to safely store vaccines.



VFC Forms Download forms for enrolling, vaccine ordering and more.



EZIZ Training

Interactive lessons, job aids, video demonstrations, and other resources.



VFC Online Ordering Place a vaccine order. Order supplemental flu vaccine. Submit a Transfer/Return.

Download ACIP's 2012 Childhood, Adolescent, and Adult Immunization Schedules

Vaccine Fact Sheets

Download these quick, easy reference documents that provide condensed vaccine information regarding: routine schedules, minimum intervals, approved for use age ranges, administration routes, billing codes, storage, ACIP recommendations and more.

Popular Links

- Printable Materials For Your Practice
- Pertussis Materials
- Flu and Respiratory Disease
- Immunization Schedule & Recommendations
- Vaccine Information
- Statements (VIS)
- CAIR Registry
- ► Disease Surveillance
- Laws and Regulations
- Local Health Departments

VFC Memos

Vaccine Order Status

- Influenza Update 2012/03/14
- Vaccine Tips: CDC's 1st Online National Immunization Conference March 2012
- Recommended ACIP Childhood and Adolescent Immunizations Schedules, 2012; Reminder, Ongoing Pertussis (Tdap) School Requirements for 7th Grade Entry; Vaccine Ordering 2012/03/02
- Vaccine Tips: Preteen Vaccine Week February 2012
- · Vaccine Tips: Features of Online Ordering and VFC Office Closure Notice January 2012
- Quadrivalent HPV Vaccine (HPV4) Now Routinely Recommended for Males 2012/01/23
- REMINDER: VFC Recertification due January 31, 2012 2012/01/20
- Influenza Supply Update 2012/01/20 Also see:

MedImmune's FluMist® 2011-2012 replacement program

- Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine
- Introducing VFC's Online Ordering System and "MyVFCVaccines" 11/14/2011 Also see: MvVFCVaccines How-to Guide Introducing MyVFCVaccines Card Vaccine Inventory Form







Flu Vaccines

- Continue giving return when expires
- Remove from unit as soon as it expires
- Return expired vaccine







New Vaccines

- Several new vaccines have been approved by the FDA.
- Need to be added to the VFC contract
- Will be available in California







Questions?

- Remember that the State Immunization Branch Field Staff and VFC Field Staff are here to help!
- Contact your area representative if you have any questions or need assistance

